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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,582	03/04/2002	Guixue Yu	HA0768 NP	5031
23914	7590	07/08/2004	EXAMINER	
STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/090,582	<b>Applicant(s)</b> YU ET AL.	
	<b>Examiner</b> Celia Chang	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1,3,4,6-8 and 11-27 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 17 and 27 is/are allowed.
- 6) ☐ Claim(s) 1,14,16,18,21-23 and 25 is/are rejected.
- 7) ☐ Claim(s) 3-4, 6-8, 11-13, 24, 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. This application is a RCE of SN 10/090,582. A pre-examination amendment was filed on May 13, 2004. Claims 2, 5, 9-10 have been canceled. Claims 23- 27 have been newly added. Claims 1, 3-4, 6-8, 11-27 are pending. A restriction/election was made and prosecution continues with the elected invention of group II, claims 16-17 and base claims 1, 3-4, 6-8, 11-15, 18-27 reading on the compounds of claims 16-17. Claims 19-20 remained withdrawn as the non-elected invention.
2. Applicant's arguments with respect to claim 1, 3-4, 6-8, 11-18, 21-27 have been considered but are moot in view of the new grounds of rejection necessitated by applicants' pre-examination amendment.
3. Claims 1, 18, 21-23, 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Particularly, it is noted that examples of one of R8 or R9 is triazolyl substituted methyl and the other one is cycloalkyl, one of R8 or R9 is benzyl and the other one of R8 or R9 is n-propyl-carbonyl were found in the specification. However, no antecedent basis nor descriptive support can be found for the subgenus as "...where one of R8 and R9 is alkyl substituted with heteroaryl and the other is cycloalkyl or where one of R8 and R9 is aryl and the other is C(=O)R13". Please note that in the preferred embodiment such specific combination was not described. On pages 30-31, the preferred R8 and R9 has been delineated to be a subset of (CH<sub>2</sub>) interpreted moieties and no particular combination for the claimed scope. Please note that an amendment to a particular combination must be supported by description and antecedent basis found in the specification. Lacking of the particular antecedent basis of the instant claimed scope, NEW MATTER was found. Removal of all new matter is required. In re Rasseussen 211 USPQ 325.

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4. Claims 21-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Please note that claims 21-22 are considered being "reach through" claims which contain subject matter to be discovered in the future i.e. any disorder not yet correlated but may be discovered in the future with the melanocortin receptor agonism.

Further, descriptive support for the instant scope is lacking because on page 2 it was disclosed that MC4R receptor agonist causes weight loss while MC4R antagonist causes weight gain. Pages 44-47 provided binding assay procedure for melanocortin receptor binding. No information of the claimed compounds to be either agonists or antagonists of the melanocortin receptor. No description or enablement was found in the specification that the claimed compound is melanocortin receptor agonist. Neither was any particular disorder or disease evidenced to be treatable by the instantly claimed compounds. While melanocortin receptor modulation may provide apparent utility for certain receptor active material, specific nexus that the instant claimed compound correlates to a class of chemical structure which ensures binding with agonism of the melanocortin receptor have not been found in the record.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 14, 16, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palucki et al. US 6,458,790 (recited in the record).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Palucki et al. '790 disclosed melanocortin-4 receptor agonistic compounds when the "W" moiety of the instant claims are drawn to piperazine. Structural similar compounds are found at col. 41-42 first two compounds and col. 45-46, 3<sup>rd</sup> compound of the table (not exhausted listing).

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the Palucki et al. '790 species and the instant claims is that instead of a heteroaryl substituted alkyl for R8 or R9, the examples at col. 41-42 first two compounds and the 3<sup>rd</sup> compound of col. 45-46 have a heterocyclic substituted alkyl. Generically, Palucki et al. '790 taught that for the "X" moiety, a heterocyclic or triazolyl substituted alkyl are optional choices for such compounds (see col. 12 line 58 triazolylmethyl, col. 14 lines 5-10, heterocyclomethyl of compounds exemplified at col. 41-42 or 45-46) and the alternative triazolylmethyl moiety has been clearly described, enabled and exemplified at col. 70.

*Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)*

One having ordinary skill in the art would find the currently amended scope, although considered to be new matter, prima facie obvious **because** the Palucki et al. '790 not only taught generically the optional choices of structural alternatives for the "X" moiety but also explicitly disclosed and enabled by exemplification of the preferred structure including the heteroaryl substituted alkyl for R8 while the R9 moiety is cyclohexyl. In absence of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814.

6. Claims 17 and 27 are allowable.

Claims 3-4, 6-8, 11-13, 15, 24 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable when the new matter issues of the base claim can be resolved.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*July 6, 2004*



*Celia Chang*  
*Primary Examiner*  
*Art Unit 1625*